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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/444,507	11/22/1999	ANDREW L. DIRIENZO	VPR-001US	8746
37119	7590	05/14/2004	EXAMINER	
MORRISON COHEN SINGER & WEINSTEIN, LLP 750 LEXINGTON AVENUE NEW YORK, NY 10022			BLECK, CAROLYN M	
			ART UNIT	PAPER NUMBER
			3626	

DATE MAILED: 05/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/444,507	DIRIENZO, ANDREW L. <i>ML</i>	
	Examiner	Art Unit	3626
	Carolyn M Bleck		

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 05 February 2004.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-19 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____. | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

Notice to Applicant

1. This communication is in response to the amendment filed 5 February 2004. Claims 1-19 are pending. Claims 1, 4, 11, 15, and 19 have been amended. No claims have been cancelled.

Specification

2. The amendments to the specification filed 5 February 2004 have been entered and considered.
3. The amendment filed 5 February 2004 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows:

The newly added recitation "without using a full electronic patient record" within claims 1, 4, 11, 15, and 19 appears to constitute new matter. In particular, Applicant does not point to, nor was the Examiner able to find any support for a digital vital patient record storing essential predetermined information for a patient "without using a full electronic patient record" within the specification as originally filed. As such, Applicant is respectfully requested to clarify the above issues and to specifically point out support for the newly added limitations in the originally filed specification and claims.

Applicant is required to cancel the new matter in the reply to this Office Action.

(B) Claims 2-3, 5-10, 12-14, and 16-18 incorporate the deficiencies of claims 1, 4, 11, 15, and 19 through dependency, and are therefore objected to as well.

Claim Rejections - 35 USC § 101

4. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. Claims 1-3 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Under the statute, the claimed invention must fall into one of the four recognized statutory classes on invention, namely, a process (or method); a machine (or system); an article of manufacture; or a composition of matter.

(A) At page 8 of the response filed 5 February 2004, Applicant argues that claim 1 is tangible and is thus statutory subject matter.

In response, firstly the Examiner notes that "a patient record" as recited in the preamble is not one of the four recognized statutory classes. It is not a process (or method); a machine (or system); an article of manufacture; or a composition of matter. Furthermore, the Examiner agrees that the elements of the claim are a "digital" record and a hard copy record. However, the Applicant states that the "patient record" as recited in the preamble of claim 1 clearly has two tangible elements: a "digital vital patient record" that exists in computer memory (or an equivalent medium) and a "hardcopy patient record." It is noted that nowhere in the claim is computer memory or a computer readable medium mentioned.

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Secondly, "a patient record" as recited in claim 1 is non-functional descriptive material, *per se*, and is not statutory. "A patient record" is simply a mere arrangement of data. The "patient record" is merely stored to be read or outputted by a computer without any functional interrelationship, and thus does not impart functionality to the computer, i.e., the "digital vital patient record" and the "hardcopy patient record" are not tied to computer components. *In re Wamerdam*, 33 F.3d 1354; 31 USPQ2d 1754 (Fed. Cir. 1994). Thus, the claimed invention taken as a whole does not produce a useful, concrete, and tangible result.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

NOTE: The following rejections assume that the subject matter added in 5 February 2004 amendment are NOT new matter, and are provided hereinbelow for Applicant's consideration, on the condition that Applicant properly traverses the new matter objections and rejections made in preceding sections above in the next communication sent in response to the present Office Action.

7. Claims 1-5, 7, 9-12, 14-16, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eberhardt (5,832,488) in view of Garcia (5,065,315), for substantially

the same reasons given in the prior Office Action (paper number 11). The reasons appear hereinbelow.

(A) Claims 1, 4, 11, and 15 have been amended to include the recitation a digital vital patient record (VPR)... “without using a full electronic patient record.”

As per this amendment, Eberhardt discloses storing a “Critical Information File” (CIF), containing critical medical information about the individual, wherein the CIF is maintained as a separate file from the medical history file (MHF) (col. 7 lines 48-67). It is noted that Eberhardt’s disclosure of a critical information file storing information for emergency situations separate from the MHF is considered to be a form of “a digital vital patient record storing essential predetermined information for a patient without using a full electronic patient record.”

The remainder of claims 1, 4, 11, and 15 have not been amended, and are therefore rejected for the same reasons given in the previous Office Action, and incorporated herein (paper number 11; sections 6(A)-6(K); pages 4-10).

(B) Claims 2-3, 5, 7, 9-10, 12, 14, 16, and 18 have not been amended and are rejected for the same reasons given in the prior Office Action (paper number 11; sections 6(A)-6(K); pages 4-10).

8. Claims 6, 8, 13, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eberhardt (5,832,488) and Garcia (5,065,315) as applied to claims 4-

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5, 7, 11-12, and 15-16 above, and further in view of Sujansky ("The Benefits and Challenges of an Electronic Medical Record: Much More than a "Word-Processed" Patient Chart", *Western Journal of Medicine*, San Francisco, vol. 169, September 1998, pages 176-183), for substantially the same reasons given in the prior Office Action (paper number 11). The reasons appear hereinbelow.

(A) Claims 6, 8, 13, and 17 have not been amended and are rejected for the same reasons given in the prior Office Action (paper number 11; section 7(A)-7(B); pages 10-11).

9. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Eberhardt (5,832,488) in view of Garcia (5,065,315) and Sujansky ("The Benefits and Challenges of an Electronic Medical Record: Much More than a "Word-Processed" Patient Chart", *Western Journal of Medicine*, San Francisco, vol. 169, September 1998, pages 176-183), for substantially the same reasons given in the prior Office Action (paper number 11). The reasons appear hereinbelow.

(A) Claim 19 has been amended to include the recitation a digital vital patient record (VPR)... "without using a full electronic patient record."

As per this amendment, Eberhardt discloses storing a "Critical Information File" (CIF), containing critical medical information about the individual, wherein the CIF is maintained as a separate file from the medical history file (MHF) (col. 7 lines 48-67). It is noted that Eberhardt's disclosure of a critical information file storing information for

emergency situations separate from the MHF is considered to be a form of "a digital vital patient record storing essential predetermined information for a patient without using a full electronic patient record."

The remainder of claim 19 has not been amended, and is therefore rejected for the same reasons given in the previous Office Action, and incorporated herein (paper number 11; section 8(A); pages 11-13).

Response to Arguments

10. Applicant's arguments filed 5 February 2004 have been fully considered but they are not persuasive. Applicant's arguments will be addressed below in the order in which they appear in the response filed 5 February 2004.

(A) At pages 8-10 of the response filed 5 February 2004, Applicant argues that the limitations of claims 1, 4, 11, 15, and 19 are not taught by the applied prior art.

In response, all of the limitations which Applicant disputes as missing in the applied references, including the features newly added in the 5 February 2004 amendment, have been fully addressed by the Examiner as either being fully disclosed or obvious in view of the collective teachings of Eberhardt and/or Garcia, based on the logic and sound scientific reasoning of one ordinarily skilled in the art at the time of the invention, as detailed in the remarks and explanations given in the preceding sections of the present Office Action and in the prior Office Action (paper number 11), and incorporated herein. One cannot show nonobviousness by attacking references

individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

In addition, it is respectfully submitted that the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

(B) At pages 9-10 of the response filed 5 February 2004, Applicant argues that the applied references cannot be combined.

In response to applicant's argument that the applied references cannot be combined, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

Conclusion

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11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Bleck whose telephone number is (703) 305-3981. The Examiner can normally be reached on Monday-Thursday, 8:00am – 5:30pm, and from 8:30am – 5:00pm on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached at (703) 305-9588.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Receptionist whose telephone number is (703) 306-1113.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

13. Any response to this action should be mailed to:

Commissioner of Patents and Trademarks
Washington, D.C. 20231

Or faxed to:

(703) 872-9306 or (703) 872-9326 [Official communications]

(703) 872-9327 [After Final communications labeled "Box AF"]

(703) 746-8374 [Informal/ Draft communications, labeled "PROPOSED" or "DRAFT"]

Hand-delivered responses should be brought to Crystal Park 5, 2451 Crystal Drive, Arlington, VA, 7th Floor (Receptionist).

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May 5, 2004

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Norman Krasner
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